Acusupply Inc.
Acupuncture & Medical products supplies

OCT 2 9 2001

ATTACHMENT "C"

September 3, 2001

PRE-MARKET NOTIFICATION 510 (K) SUMMARY (AS REQUIRED BY 21 CFR 807.92)

Submitter:	Acusupply Inc. 3801 NE 207th Street Suite 501 Aventura Fl 33180 phone: 305 932 9413
Contact Person:	Feres Dáger
Date Summary prepared:	September 3, 2001
Name of Device	Acupuncture needles under the brand name of "CW-ACUPUNCTURE NEEDLES
Common or usual name:	Acupuncture needles
Classification:	Class II
510(k) Number	K011248

Substantially Equivalence:

The C W Acupuncture needle is substantially equivalence in design, materials and performance to other acupuncture brands of those, which were in commercial distribution before May 28, 1976,except for the sterilization method which is Gamma ray. It is also equivalent to acupuncture needles which have been found to substantially equivalent through the 510 (k) Premarket process.
These are:

CW Acupuncture needles (Same product different importer)	K 964529 (01-30-97)

3801 NE 207th street Aventura Fl 33180
Phone: 305 932 9413
Fax: 305 932 3783
Email: acusuply@bellsouth.net
URL:https// acusupplyonline.com

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Acupuncture & Medical products supplies

PRE-MARKET NOTIFICATION 510 (K) SUMMARY (continued)

Description of device:

The CW needles are sterile disposable, surgical s/steel, with a spiral wound silver or cupper handles mechanical attached. The needles are supplied in bulk hot sealed packaged with one polypropylene insertion tube. Ten of those needles inside a polypropylene bag. Then 10 of those bags are packed in a paper carton box. A "Prescription"; "For single use only"; "Pyrogen free"; and made in Korea statements are shown in box labeling.

Intended use:

They are used to pierce the skin in the practice acupuncture (by qualified practioners of acupuncture) as determined by the state. They are not suitable for home use.

Comparison:

The CW needles have the same technological characteristics as the predicate devices identified before. They are manufactured in same lengths and gauges (thickness); handle length and design (spiral wound mechanical attached); and packaging methods are the same. The validation of sterilization method is based on AAMI Radiation Standard Method 1; the minimum gamma ray dose is 25 kGy which is according to the required regulations. The method of insertion in polypropylene bags is the same use for the predicates.

Substantial equivalence is not based on an assessment of performance data.

Feres Dáger, Marketing director

September 3, 2001

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2001

Mr. Feres Dager
Marketing Director
AcuSupply, Incorporated
3801 NE 207th Street, Suite 501
Aventura, Florida 33180

Re: K011248
Trade/Device Name: CW Disposable Acupuncture Needle
Regulation Number: 880.5580
Regulation Name: Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: September 4, 2001
Received: September 28, 2001

Dear Mr. Dager:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011248

Attachment "B"

510(k) Number (if known): K 011248

Device Name: **Acupuncture needles under the brand name of "CW-ACUPUNCTURE NEEDLES"**

Indications For Use.

"CW-ACUPUNCTURE NEEDLES" are used to pierce the skin in the practice of Acupuncture by qualified practioners, as determined by the States.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011248

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